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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/273,230	03/18/1999	JEFFREY L. CLELAND	P0998D1	6833

7590

08/22/2002

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EXAMINER

YAEN, CHRISTOPHER H

ART UNIT

PAPER NUMBER

1642

DATE MAILED: 08/22/2002

16

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/273,230

Applicant(s)

CLELAND ET AL.

Examiner

Christopher H Yaen

Art Unit

1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 May 2002.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 42-49 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 42-49 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)                      4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)                      5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_                      6) ☐ Other: \_\_\_\_\_

Art Unit: 1642

### **DETAILED ACTION**

1. The examiner of the application has changed. This case has now been transferred as of 8/5/02. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Christopher Yaen, Group Art Unit 1642.

#### ***Continued Examination Under 37 CFR 1.114***

2. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 5/21/02 has been entered.

3. The amendments filed 5/21/02 (paper no 16) are acknowledged and entered. Claim 43 has been canceled without prejudice. Claims 42, 44-49 are pending and are examined on the merits.

#### ***Information Disclosure Statement***

4. The Information Disclosure Statements filed 7/14/99, 12/27/99, 2/28/01 have not been associated with the file. Applicant is requested to refile the IDS and/or show proof of filing for consideration on the next office action on the merits.

#### ***Claims Rejections Withdrawn***

Art Unit: 1642

5. The rejection of claim 42, and 44-49 under 35 USC 112, 1<sup>st</sup> paragraph as lacking an enabling disclosure that is commensurate in scope to the claims of the instant application, is **withdrawn**, upon further reconsideration, a new rejection follows.

***New Claim Rejections***

***Claim Rejections - 35 USC § 103***

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 42-49 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hudziak *et al* (US. Pat No. 5770195) in view of Hudziak *et al* (US Pat No. 5720954) and Burton SC *et al* (Am J Vet Res 1981 Feb;42(2):308-10).

Claims 42-49 are drawn to a method of treating cancer characterized by over expression of Her2 receptor in a mammal comprising the administration of a Her2

Art Unit: 1642

receptor antibody, which is lyophilized, wherein the mammal is a human. The claims are also directed to the treatment of specific cancer types. Furthermore, the claims are directed to a specific concentration of antibody for administration. Because the amount of antibody formulation actually administered is not disclosed in the instant claims, the claims are interpreted as any dosage when administered.

Hudziak *et al* (US Pat No. 5770195) teach a method of treating cancer, through the inhibition of tumor cells, comprising the administration of a HER receptor antibody. Hudziak *et al* also specifically teach the treatment of specific cancer types. Hudziak *et al*, however do not specifically disclose of dosages nor does Hudziak *et al* disclose of lyophilization of an antibody.

Hudziak *et al* (US Pat No. 5720954) teach of administering a Her2 receptor antibody in a specific dosage to a patient to treat cancer. Burton *et al* disclose a formulation of an antibody to be administered to a patient in a lyophilized form.

Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to devise of a method to treat cancer with a Her2 receptor antibody, that was lyophilized in any dosage range, because Hudzaiak *et al* (US Pat No. 5770195) taught of a method for treating cancer by administering a Her2 receptor antibody, Hudziak *et al* (US Pat No. 5720954) taught that administration of a Her2 receptor antibody in a dosage was effective in treating cancer, and Burton *et al* taught that an antibody in lyophilized form can be used effectively when administered to patients. One of skill in the art would have been motivated to perform the instant method because Hudzaik *et al* (US Pat No. 5770195 and 5720954) already disclosed

Art Unit: 1642

both the treatment of cancer with a Her2 receptor antibody and the treatment at specific dosages, and Burton *et al* disclosed the preparation and administration of an antibody in lyophilized form to a patient. One of ordinary skill in the art could expect a reasonable amount of success in attempting the instant method, because an antibody to Her2 receptor had already been disclosed as being effective in treating cancer at certain dose ranges, and the preparation and administration of an antibody to a patient was also already proven to be effective in immunological responses.

### ***Conclusion***

9. No claim is allowed.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher H Yaen whose telephone number is 703-305-3586. The examiner can normally be reached on Monday-Friday 9-5.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Application/Control Number: 09/273,230  
Art Unit: 1642

Page 6

Christopher Yaen  
Art Unit 1642  
August 9, 2002

  
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SUPERVISORY PATENT EXAMINER  
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